

71QSCI16138005 Scopes and Scope Equipment (36620653060085) ONE LOT CONSISTING OF 1 SONY MONITOR TV MODEL 8202215, 1993, 1 OLYMPUS LIGHT SOURCE MODEL CLK-4 2005, 1 OLYMPUS COLOR VIDEO PRINTER MODEL OPE-3 JANUARY 2001, 1 MAINTENANCE UNIT MODEL MU-1 TESTER OCTOBER 2001, 1 CAMERA MODEL UNKNOWN AUGUST 1999 , 1 XENON POWER SUPPLY MODEL DYOBRITE3000 JANUARY 1996, 1 OLYMPUS INSUFFLATOR MODEL A56441 SEPTEMBER 1993, 1 FLUSHING PUMP ENDOSCOPE SYS PCI MEDICAL ENDO-FLUSH MODEL EFP250, 1 NASOPHARYNGO-LARYNGOSCOPE MODEL ENT-2000 JULY 2007, 1 TRACHEAL INTUBATION FIBERSCOPE MODEL LF-DP AUGUST 2007, 1 CHOLEDOCHOFIBERSCOPE TRANSLAPAROSCOPIC MODEL CHF-CB30L JUNE 2008, 1 OLYMPUS THORACOFIBERSCOPE MODEL UNKNOWN OCTOBER 1993, 1 OLYMPUS NASOPHARYNGO-LARYNGOSCOPE MODEL ENT-2000 SEPTEMBER 2007, 1 OLYMPUS BRONCHOSCOPE MODEL BF-1T30 MARCH 2005, 1 PENTAX MODEL ED-3430T VIDEO DUODENOSCOPE UNITS ENCLOSED IN A NICE ROLL AROUND CABINET AS SHOWN.

REPAIRS REQUIRED.

\*\* WINNING BIDDER REQUIRED TO COMPLETE AND SUBMIT THE ATTACHED "71QSCI16139005 MEDICAL DEVICES SOI.PDF" PRIOR TO REMOVAL. E-MAIL TO MARK.MAXWELL@GSA.GOV WITH A CC TO MICHAEL.ALBERTSON@VA.GOV IS THE PREFERRED METHOD OF SUBMISSION\*\*

**MEDICAL DEVICES.** Purchasers of all medical equipment listed in the Invitation for Bid (IFB) shall certify and assure in writing that such item will be used or resold only under the conditions specified below:

Medical device items are subject to the laws and regulations administered by the Food and Drug Administration (FDA). Provisions of the governing statute, the Federal Food, Drug and Cosmetic Act appear in 21 U.S.C. 331, ET. Seq. In summary, the Act prohibits the movement in interstate commerce of medical devices that are misbranded or adulterated. The Act authorizes FDA to initiate criminal enforcement proceedings against companies and/or individuals responsible for violations of its provisions. Moreover, the Act authorizes FDA to initiate civil proceedings to seize, or enjoin the distribution of such items.

It shall, also, be the responsibility of all purchasers to comply with local, state, or other applicable laws.

The following certificate, to be a separate attachment to the Invitation for Bid, is required by FDA to purchase the medical device items identified in the Invitation.

I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the manufacture and/or refurbishing of the medical device item identified in the IFB. I, also, certify that prior to sale or use of such a device, I will take assurance that such a device is not adulterated or misbranded within the meaning of those terms in the Federal Food Drug and Cosmetic Act (21 U.S.C., et Seq.).

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**Signature**

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**Date**

Recognizing that Federal law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C. 331, et. Seq.), I certify that I either will sell or otherwise proffer the medical device item identified in the IFB to persons described in the above, or will not use this item(s) for their original or usual intended use, for any other medical use.

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**Signature**

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**Date**

False or misleading statements may result in a fine of not more than \$10,000 or imprisonment for not more than five (5) years, or both (18 U.S.C. 1001).